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FACT SHEET

TCE Toxicity Information: Implications for Chronic and Shorter-Term Exposure

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Trichloroethylene ("TCE") is a common contaminant at disposal sites being assessed and remediated pursuant to M.G.L. Chapter 21E and the Massachusetts Contingency Plan ("MCP", 310 CMR 40.0000). This Fact Sheet provides a summary of the toxicity information for TCE for use in MCP risk characterizations, including Imminent Hazard Evaluations, and the application of this information to the assessment of disposal sites.

Specific questions about the assessment and cleanup of TCE at MCP sites may be addressed to BWSC.Information@state.ma.us.

1. Available Chronic Toxicity Information for TCE

In September, 2011, the U.S. Environmental Protection Agency ("USEPA") released its Final Assessment for TCE on its Integrated Risk Information System ("IRIS"). This Final Assessment for TCE is available online at <http://www.epa.gov/iris/subst/0199.htm>. The following toxicity information was included in the September 2011 update:

- Reference Dose for Chronic Oral Exposure ("RfD") = 5×10^{-4} mg/kg/day
- Reference Concentration for Chronic Inhalation Exposure ("RfC") = 0.002 mg/m^3 ($2 \text{ } \mu\text{g/m}^3$)
- Quantitative Estimate of Carcinogenic Risk from Oral Exposure
Oral Slope Factor = 5×10^{-2} per mg/kg-day
- Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure
Inhalation Unit Risk = 4×10^{-6} per $\mu\text{g/m}^3$

**Target Risk Level Using September 2011 TCE Toxicity Values
(Residential Exposure Scenario)**

Method 3 Assessments	Estimated Indoor Air Concentration	Health Effect (new IRIS value)
No Significant Risk^{1,2} (Risk Driver)	2 µg/m³ (Chronic Exposure Noncancer Risk, HQ=1)	Fetal developmental and immune system effects (all receptors)

Table Notes:

(1) The risk-based estimate assumes a single chemical and single exposure route. Consideration of the Cumulative Receptor Risk from multiple exposure pathways and/or multiple chemicals with the same target organ/mechanism of action may further reduce the concentration associated with No Significant Risk on a site-specific basis. Conversely, a quantitative risk assessment that calculates a site-specific Hazard Quotient using residential exposure input parameters may conclude that incrementally higher concentrations – as high as 2.9 µg/m³ – also equate to a Hazard Quotient = 1 (rounded to one significant figure).

(2) This concentration is based upon a residential exposure. Site-specific adjustments such as for exposure frequency, may be appropriate for workplace settings and could result in somewhat higher indoor air concentrations associated with No Significant Risk.

MassDEP is highlighting these updated toxicity factors for use in the evaluation of chronic exposures under the MCP pursuant to 310 CMR 40.0993(5)(a). The MassDEP Risk Assessment ShortForms have been updated to reflect the USEPA TCE toxicity values.¹ The Department is also finalizing MCP Method 1 soil and groundwater standards and MCP Reportable Concentrations for soil and groundwater based on these values.

2. Consideration of Short-term (Subchronic or shorter) Exposures to TCE

Short-term exposure to TCE is evaluated pursuant to the MCP in part to determine if an Imminent Hazard exists at a site. An Imminent Hazard determination may be based on either excessive cancer- or noncancer-risk.

The IRIS Toxicological Review for TCE describes the basis for the chronic RfD and chronic RfC. One of the health endpoints is increased fetal cardiac malformations observed in laboratory animals exposed *in utero* to TCE. There is also some human evidence of developmental heart defects from TCE exposure in community studies (EPA/635/R-09/011F, Section 4.8.3.1.1). Because this health endpoint, by definition, is the result of a short-term exposure (during gestation), the chronic RfD and chronic RfC provide important information to incorporate into the evaluation short-term exposures to TCE, including the potential for Imminent Hazards based on potential noncancer risk.

Some USEPA Regions and the Agency for Toxic Substances and Disease Registry (“ATSDR”) have recently relied on the chronic RfC value to evaluate shorter-term exposures. The USEPA is still reviewing the toxicology studies before publishing specific recommendations for short-term exposures. Recently, stakeholders have raised concerns about the use of these developmental studies. The timeframe and outcome of the USEPA review is uncertain.

¹ The Risk Assessment ShortForms are available online at:
<http://www.mass.gov/eca/agencies/massdep/toxics/sources/riskasmt-htm.html#7>

3.0 Target Risk Levels Inferred from the September 2011 TCE Toxicity Values

The Department conducted a review² of the toxicological information available for TCE in consultation with the MassDEP Health Effects Advisory Committee that resulted in the recommendations for action described in the table below. This review addressed several issues associated with the use of the 2011 TCE toxicity values:

- Confidence in the chronic Reference Dose and Reference Concentrations;
- Appropriateness of using the same studies/numerical values to evaluate short-term exposures, including whether the values should be adjusted to reflect their application to a shorter exposure period; and
- Implementation concerns, including appropriate exposure frequency and duration factors to use for residential and non-residential exposure scenarios, and the timing of necessary response actions to address any identified Imminent Hazards.

The recommendations correspond to the use of the USEPA chronic Reference Concentration ("RfC") of 2 µg/m³ adjusted by a factor of three (3) to address short-term exposure concerns. (This adjustment factor of 3 is specific to TCE and this RfC.) Measured indoor air sampling data can be compared to the values in the table below to determine the level of concern for residential and non-residential buildings, and whether the conditions could or would pose an Imminent Hazard.

A site-specific Imminent Hazard Evaluation may be conducted if the exposure assumptions incorporated in Table 3 do not apply to the affected building. The USEPA RfC should be used in combination with the recommended adjustment factor of 3. Therefore, the Hazard Quotient calculations would be:

$$IH\ HQ_{TCE} = \frac{[Measured\ Site\ Concentration]}{[USEPA\ RfC] \times 3} \quad (1)$$

Another option is to use the ORS ShortForms tools to establish whether an Imminent Hazard exists at a given location. ShortForm "sf12osaih" can be used to conduct an Imminent Hazard Evaluation at offices and schools and ShortForm "sf12raih" can be used to conduct an Imminent Hazard Evaluation at residences. [Note that the ShortForms do not include the adjustment factor of 3 and therefore provide results that are 3 times more stringent than those resulting from Equation (1).]

MassDEP understands that the U.S. EPA may prepare additional guidance on this issue as well. The Department will continue to monitor recommendations from the U.S. EPA and other state and federal public health and environmental agencies. This Fact Sheet will be updated as needed to reflect relevant developments from the ongoing state and federal review efforts.

² The MassDEP review is available online at <http://www.mass.gov/eea/agencies/massdep/toxics/sources/chemical-research-and-standards.html>.

Pregnant Women and Those Who May Become Pregnant

<i>Residential Exposure Scenario³</i>	Indoor Air Concentration	Concern Level	Actions
Fetal developmental effects (Subchronic Exposure Noncancer Risk, HQ=1)	> 6 µg/m ³	Imminent Hazard 2-hr Notification	Immediate Response Action Goal to reduce levels to <u>at least</u> less than 6 µg/m ³ ASAP (within several days if possible)
<i>Workplace Exposure Scenario⁴</i>	Indoor Air Concentration	Concern Level	Actions
Fetal developmental effects (Subchronic Exposure Noncancer Risk, HQ=1)	> 24 µg/m ³	Imminent Hazard 2-hr Notification	Immediate Response Action Goal to reduce levels to <u>at least</u> less than 24 µg/m ³ ASAP (within several days to a week if possible)

All Receptors

<i>Residential Exposure Scenario</i>	Indoor Air Concentration	Concern Level	Actions
Immune system effects (Subchronic Exposure Noncancer Risk, HQ=10)	> 20 µg/m ³	Imminent Hazard 2-hr Notification	Immediate Response Action initiated on an expedited time table
<i>Workplace Exposure Scenario</i>	Indoor Air Concentration	Concern Level	Actions
Immune system effects (Subchronic Exposure Noncancer Risk, HQ=10)	> 90 µg/m ³	Imminent Hazard 2-hr Notification	Immediate Response Action initiated on an expedited time table

Table Notes:

- (A) The risk-based estimate assumes a single chemical and single exposure route, calculated using the Risk Assessment ShortForm to identify the concentration associated with a Hazard Quotient equal to 1. Consideration of the Cumulative Receptor Risk from multiple exposure pathways and/or multiple chemicals with the same target organ/mechanism of action may further reduce the concentration associated with an Imminent Hazard on a site-specific basis. Conversely, a quantitative risk assessment that calculates a site-specific Hazard Quotient using standard exposure input parameters may conclude that incrementally higher concentrations – as high as 8.6 µg/m³ for residential Imminent Hazards or 36 µg/m³ for workplace Imminent Hazards – also equate to a Hazard Quotient = 1 (rounded to one significant figure).
- (B) Site-specific adjustments such as for exposure frequency may be appropriate, such as for the workplace setting illustrated here. On a case-specific basis, the calculation could result in different (even somewhat higher) indoor air concentrations associated with Imminent Hazards.

³ Sensitive receptors are pregnant women and women who may become pregnant assumed to be exposed 24 hours/day, 7 days/week, such as in a residential setting.

⁴ Sensitive receptors are pregnant women and women who may become pregnant assumed to be exposed 8 hours/day, 5 days/week, such as in an office setting.

4. MassDEP Approach for Addressing TCE Imminent Hazards

Applicable Risk management Criteria: The health effect of concern, increased fetal cardiac malformation, is a developmental effect. The MCP (at 310 CMR 40.955(2)(c)1.) requires the use of a Hazard Quotient of 1 for Imminent Hazard evaluations of chemicals that cause development effects. (The MCP Risk Assessment ShortForms have been updated with a notation indicating concerns about developmental effects that necessitate the use of a Hazard Quotient = 1 to manage potential risks.) Conditions that pose or could pose an Imminent Hazard require notification to MassDEP within 2 hours of obtaining knowledge of the condition.

Timing and coordination of Immediate Response Actions: The MCP requires the implementation of Immediate Response Actions to abate, prevent or eliminate any Imminent Hazards identified at a site. Since the exposure duration of concern for developmental health effects is short – measured at most in days – MassDEP will work with responding parties to identify appropriate mitigation options and begin implementation quickly for locations where pregnant women or women who may become pregnant are present. The MassDEP *Interim Final Vapor Intrusion Guidance* (WSC #11-435, <http://www.mass.gov/dep/cleanup/laws/vifin.pdf>) includes a discussion of vapor intrusion pathway mitigation measures (Chapter 3). While the sequential approach to implementing mitigation measures described in the guidance is relevant to these TCE exposure conditions, the time-frame for implementation and subsequent evaluation must be expedited for locations where pregnant women or women who may become pregnant are present in consideration of the potential for developmental effects. In order to maintain an accelerated schedule, the preparation and planning for possible subsequent response actions must begin immediately and should not be delayed until the monitoring results are fully assessed.

[Note that the low TCE concentrations that pose an Imminent Hazard in a residential setting may limit the feasibility considerations of the Critical Exposure Pathway (CEP) provisions.]

Initial response actions that should be implemented immediately include:

- Ensure appropriate Fact Sheets are provided to Affected Individuals;
- Vent the basement (if a basement exists in the building) or lowest level of the building by opening windows;
- Seal cracks/utility annular spaces in bottom floor of building and subsurface walls; and
- Enclose and passively vent sumps.

Response actions that should be implemented as soon as possible, but which may require several days to two weeks to arrange and implement include:

- Adjust the HVAC system (if applicable) to provide outside make-up air for heating and cooling system combustion/drafting and over-pressurize building's interior
- Install carbon filtration on HVAC system; and
- Bring portable air-purifying units (APUs) to the affected building [note: to be effective, an adequate number of APUs is needed based upon the volume of the affected area of the building (in cubic feet)].

Response actions that should be implemented as soon as possible, but which may require several weeks to two months to design, construct and test include:

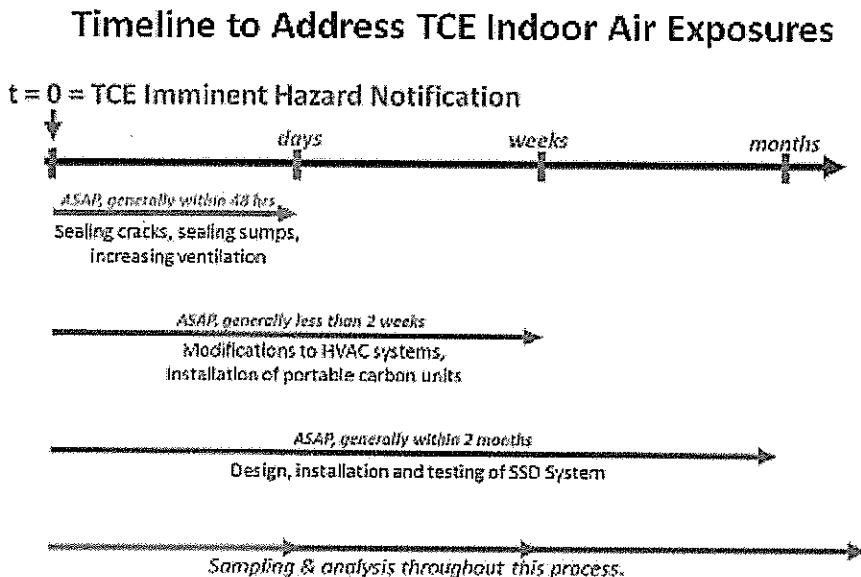
- Installation of a sub-slab depressurization system
- Installation of air-to-air heat exchanger to over-pressurize the basement
- Installation of a soil vapor extraction system

After each response action is implemented, indoor air may be sampled, analyzed and evaluated to determine the effectiveness of the response action and the need for additional actions. All response actions shall be monitored, as appropriate, including indoor air concentrations, mechanical operations, pressure, vacuum, flow rate, sub-slab negative pressure fields, and/or sub-slab soil gas concentrations.

In order to maintain an accelerated schedule, the preparation and planning for subsequent response actions should occur concurrent with the analysis and evaluation of prior response actions, so that if subsequent actions are necessary they may be implemented as soon as possible.

Mitigation of the vapor intrusion pathway is difficult and under the best of circumstances may take more than a week to confirm that initial actions have eliminated IH conditions. Where TCE concentrations are found to be well above the IH criteria – where they exceed $20 \mu\text{g}/\text{m}^3$ in a home or $60 \mu\text{g}/\text{m}^3$ in a workplace - DEP should be consulted about available short-term options for reducing or eliminating exposures to pregnant women (or women who may be pregnant) while response actions are developed and implemented.

Figure 1 – Recommended Timeline for Response Action Implementation



MassDEP has prepared additional material, including a template Notice to Affected Individuals” and “Frequently Asked Questions” for residential and workplace TCE sites. These documents are available online at <http://www.mass.gov/eea/agencies/massdep/cleanup/regulations/tech-support-docs.html> and <http://www.mass.gov/eea/agencies/massdep/toxics/sources/chemical-research-and-standards.html>